UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

UNITED STATE OF AMERICA)	Civil Action No.17-11644
Ex. Rel. RONALD KUFNER, M.D.	
SANJIT JAYAKAR)	FILED IN CAMERA AND
,)	UNDER SEAL
Plaintiffs,)	
)	FALSE CLAIMS ACT
vs.)	MEDICARE AND
	MEDICAID FRAUD
THE PAIN CENTER USA, PLLC,)	
INTERVENTIONAL PAIN CENTER, PLLC,)	JURY TRIAL DEMANDED
AND RAJENDRA BOTHRA, M.D.	•
Defendants.	·

PLAINTIFFS' COMPLAINT PURSUANT TO 31 U.S.C. 3729-3732

NOW COMES, Co-Relators RONALD KUFNER, M.D. and SANJIT JAYAKAR, by and through their attorneys, AKEEL & VALENTINE, PLC and bring this action filed by Co-Relators pursuant to the Qui Tam provisions of the False Claims Act to recover damages and penalties arising from the submission of false claims to the United States, the Federal Medicare Program, and to the State of Michigan Medicaid Programs. The claims amount to millions of dollars for payment of false billings, among other fraudulent acts.

PARTIES

1. Co-Relator Ronald Kufner, M.D. is a citizen of the United States of America and a resident of the State of Michigan, County of Oakland. Dr. Kufner

is a physician in active practice and is double-boarded in Anesthesiology and Pain Medicine by the American Society of Anesthesiology. Dr. Kufner was and is employed by Defendants, The Pain Center USA, PLLC ("TPC") and Interventional Pain Center, PLLC ("IPC"), in some capacity, and at all pertinent times herein.

- 2. Co-Relator Sanjit Jayakar is also a citizen of the United States of America and a resident of the State of Michigan, County of Oakland. Mr. Jayakar served as the Chief Operating Officer for Defendants where he maintained full oversight of all personnel, all departments, and all processes that occurred within Defendants' facilities. Co-Relator Sanjit Jayakar was employed by Defendants, in some capacity, in early 2015, and remained there until he was terminated on December 31, 2016.
- 3. Defendant TPC is a professional limited liability company with two offices, located at 27423 Van Dyke, Warren, MI 48093, and 22480 Kelly Road, Eastpointe, MI 48201. Defendant, TPC, is a medical practice that is owned, operated, and/or controlled by Defendant Bothra.
- 4. Defendant IPC is a professional limited liability company which is also located at 27423 Van Dyke, Warren, MI 48093. IPC is also a medical practice owned, operated, and/or controlled by Defendant Bothra.

- 5. Defendant Rajendra Bothra is a doctor, and a graduate from Rajasthan University in Bikaner, Rajasthan, India, and currently owns, controls, and operates both corporate Defendants, TPC and IPC.
- 6. Co-Relators are suing on their own behalf, and on behalf of, and in the name of, The United States of America, pursuant to 31 USC 3730(b) and the State of Michigan, pursuant to the *qui* tam provision of Michigan's Medicaid False Claim Act, MCL 400.610a(2).
- 7. Co-Relators have complied with notice provisions of both the Federal False Claims Act, 31 USC 3730(b)(2) and the Michigan Medicaid False Claims Act, MCL 400.610a(2) by providing the Attorney General of the United States for the Eastern District of Michigan, and the Michigan Attorney General, Health Care Fraud Division, simultaneous with the filing of this complaint, with a statement of material evidence and information related to this complaint, which support the existence of the false claims by Defendant. (Exhibit A)

JURISDICTION AND VENUE

- 8. This Court has jurisdiction in this matter under 31 USC 3732(a) and 28 USC 1331 and 1345.
- 9. Further, this court may retain Co-Relators' state claims, the Michigan Medicaid False Claim Act claim, pursuant to its discretion to exercise pendant jurisdiction over that claim. Pendant jurisdiction is proper in this case because Co-

Relators' federal FCA claim is sufficiently substantial to support federal question jurisdiction; the FCA and Michigan FCA claims derive from a common nucleus of operative facts; and the nature of the FCA and Michigan FCA claims are such that judicial economy would be achieved and Co-Relators would expect that they be tried in one proceeding.

- 10. Venue is proper in the United States District Court for the Eastern District of Michigan, Southern Division pursuant to 31 USC 3732(a) and 28 USC 1391(b)(c) because all claims were originated from Defendant's principal place of business located in Macomb County, State of Michigan.
- 11. Co-Relators have direct and independent knowledge within the meaning and definition of 31 U.S. C. 3730(e)(4)(B) derived through and from Co-Relators relationship with Defendants at one or more of their facilities, of the information on which the allegations set forth in this Complaint are based. Furthermore, Co-Relators are persons qualifying as the original source of information pursuant to MCL 400.610a(13)
- 12. None of the allegations set forth in this Complaint are based on a public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a Congressional, administrative or general accounting office report, hearing, audit, investigation or from the news media.

FACTS

MEDICARE AND MEDICAID PROGRAMS

- 13. The United States administers the Federal Medicare Program through its agency, The Department of Health and Human Services (DHHS), The Center for Medicare and Medicaid Services (CMS), which was previously known as the Health Care Finance Administration. CMS is authorized to enter into and administer contracts on behalf of DHHS and the United States.
- 14. Inherent in CMS's contracting authority is the responsibility for administering the Federal Medicare Program and Medicaid payments.
- 15. Claims relating to Medicare reimbursement are sent to and processed through the Center for Medicare and Medicaid Services (CMS).
- 16. DHHS, through CMS, provides health insurance to eligible aged and disabled Americans (Medicare beneficiaries) pursuant to the provisions of the Medicare Program, Title XVIII of the Social Security Act, 42 USC 1395, et. seq. The Medicare Program provides health care services and benefits to certain eligible groups such as persons over age sixty-five, disabled persons and qualifying homebound persons in need of medical and nursing care. The Medicare Program is administered under two distinct parts.
- 17. Medicare Part A, "Hospital Insurance for the Aged and Disabled", covers health care services furnished by hospitals, home health agencies, hospices,

and skilled nursing facilities. Medicare Part B, "Supplementary Medical Insurance for the Aged and Disabled", covers laboratory services, X-rays, physicians' services and other non-institutional services, such as medical supplies and durable medical equipment (DME), as well as some other services not reimbursed under Medicare Part A.

- 18. The State of Michigan administers a Medicaid program consistent with the federal rules and regulations and processes payments to approved healthcare providers, including Defendants.
- 19. In Michigan, under MCL 400.105, the state Department of Community Health has been authorized to establish a program of medical assistance for the medically indigent pursuant to Title XIX. In establishing this program, the term "professionally accepted standards" is defined as "those standards developed by peer review advisory committees and professionals and experts with whom the director is required to consult." *Id.* Under this section, "provider" means an "individual, sole proprietorship, partnership, association, corporation, institution, agency, or other legal entity, who has entered into an agreement of enrollment specified by the director pursuant to MCL 400.111b(1)(c)."
- 20. Each provider is required to meet certain conditions to participate in the Medicaid program. MCL 400.111b. That statute provides in part:

- (22) It is the obligation of a provider to assure that services, supplies, or equipment provided to, ordered, or prescribed on behalf of a medically indigent individual by that provider will meet professionally accepted standards for the medical necessity, appropriateness, and quality of health care."
- 21. By becoming a participating provider in Medicaid, enrolled providers agree to abide by the rules, regulations, policies and procedures governing claims for payment, and to keep and allow access to records and information as required by Medicaid. In order to receive Medicaid funds, enrolled providers are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, ClviS standards, and all applicable policies and procedures issued by the State.
- 22. Among the rules and regulations which enrolled providers agree to follow are to: (1) bill only for covered services which are medically necessary; (2) neither bill for any services or items which were not performed or delivered in accordance with applicable policies nor submit false or inaccurate information relating to provider costs or services; (3) not engage in any act or omission that constitutes or results in over utilization of services; (4) be fully licensed and/or certified under the applicable state and federal laws to perform the services provided to recipients; (5) comply with state and federal statutes, policies and regulations applicable to the Medicare and Medicaid programs; and (6) not engage in any illegal activities related to the furnishing of services to recipients.

- 23. As detailed below, Defendants submitted claims both for specific services provided to individual beneficiaries and claims for general and administrative costs incurred in treating Medicare and Medicaid beneficiaries.
- 24. Defendants knew, or should have known that federal and state Medicare and Medicaid laws and regulations require all forms and requests for payments submitted to the respective governmental departments to be truthful, accurate, and complete. Furthermore, Defendants and their owners, officers and board of directors knew, or should have known that federal and state Medicare and Medicaid laws and regulations require that they promptly correct any errors or omission that come to their attention after being submitted to a government department.
- 25. Defendants knew, or should have known that federal and state Medicare and Medicaid laws and regulations require providers to assure that services, supplies, or equipment provided, ordered, or prescribed on behalf of a medically indigent individual by that provider will meet professionally accepted standards for the medical necessity, appropriateness, and quality of health care.
- 26. Defendants knew, or should have known that federal and state Medicare and Medicaid laws and regulations require a corporation providing medical services to be in compliance with State laws, including those requiring their corporation to be registered, and in fact operate, as a professional services

corporation, including the reasons and healthcare policies behind those requirements.

- 27. At all times relevant to this Complaint, the Medicare and Medicaid programs constituted a significant source of gross patient revenue for Defendants. Defendants provide many different services, some which are used to solicit government funds. The services provided by Defendants include, but are not limited to, 1) Interventional Pain Management, 2) Anesthesiology, 3) Physical Medicine and Rehab, 4) Psychology, 5) Psychiatry, 6) Physical Therapy, 7) Pharmacy, 8) Durable Medical Equipment, and 9) Home Care. Co-Relators have knowledge of Defendants fraudulently soliciting funds from the government for Interventional Pain Management, Anesthesiology, Physical Medicine and Rehab, Physical Therapy, and Durable Medical Equipment.
- 28. As described below, Defendants have engaged in a calculated scheme to defraud the United States Government and State of Michigan, by among other things, improperly billing Medicare and Medicaid for services; improperly billing Medicare and Medicaid for equipment and supplies; improperly billing Medicare and Medicaid under a certified doctor's name, even though the work was done by other doctors ineligible to bill for Medicare and Medicaid; improperly billing for procedures by claiming that such procedures were done in an Ambulatory Surgery Center (ASC) when in reality such procedures were done in an uncertified

operating room; improperly billing Medicare and/or Medicaid for unnecessary back braces, shoulder braces, and other equipment; improperly billing for services that do not meet acceptable standards; and other improper and illegal acts causing false claims to be submitted.

FALSE CLAIMS ACTS

- 29. The Federal False Claim Act provides, in pertinent part, as follows:
 - (a) Liability for certain acts. Any person who
 - (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
 - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
 - (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
 - (4) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt.
- 30. The Michigan Medicaid False Claim Act provides, in pertinent part, as follows:

Michigan Compiled Laws 400.603:

- (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits.
- (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit.
- (3) A person, who having knowledge of the occurrence of an event affecting his initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf he has applied for or is receiving a benefit, shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled.

FRAUDULENT BILLING FOR SERVICES

- 31. Co-Relators incorporate by reference each and every preceding paragraph as if each was set forth again at length here, sentence for sentence and word for word.
- 32. Defendants, TPC and IPC, are medical practices owned, controlled and/or operated by Defendant Rajendra Bothra. In order to bill for surgical procedures in the IPC, surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC. Defendants currently employ at least six practicing doctors at the IPC. Of the practicing doctors, and at relative times herein, some of the doctors were/are ASC credentialed which allows them to receive Medicare and Medicaid funds from certain insurers capable of retroactively administering government Medicare and

Medicaid funds. These insurers include, Aetna (AE), Blue Cross Complete (BCC), Total Health Care (THC), and Meridian (ME). Several of the other doctors were/are not credentialed, at all relevant times herein, and therefore services performed by those doctors should not be used to solicit Medicare and Medicaid funds for services that they render.

- Defendant Bothra is responsible for determining how to categorize the 33. services done by the non-credentialed doctors, and Co-Relators have knowledge of Defendant Bothra intentionally and improperly categorizing those services so to fraudulently solicit Medicare and/or Medicaid funds from the government. As such, many of the actual medical treatment that have been performed by those noncredentialed doctors have been attributed and billed in the names of the credentialed doctors, although the latter did not perform the treatment. In other words, Defendants would simply bill for work performed under a credentialed doctor's name, even though such work was actually performed by a noncredentialed doctor. This, in effect, allowed Defendants to fraudulently solicit Medicare and Medicaid funds from the government. (Exhibit B, Pictures showing Defendants' fraudulent attributing of services done by an uncertified doctor, to that of a certified doctor).
- 34. For example, work done by a Dr. Lewis (a non-credentialed doctor), was repeatedly billed under Dr. Kufner's name (credentialed doctor and the Co-

Realtor). This was unbeknownst to Dr. Kufner. See examples of fraudulent billings below that Dr. Kufner discovered:

Document ID	Date	Doctor	Health Provider	Billed Under	Treatment 1
0001	12/10/16	LEWIS	THC	KUFNER	01992
0002	12/3/16	LEWIS	THC	KUFNER	01992
0003	12/3/16	LEWIS	THC	KUFNER	01992
0004	12/3/16	LEWIS	THC	KUFNER	01992
0005	12/3/16	LEWIS	THC	KUFNER	01992
0006	01/06/17	LEWIS	THC	KUFNER	01992
0007	01/06/17	LEWIS	THC	KUFNER	01992
0008	01/06/17	LEWIS	THC	KUFNER	01992
0009	01/06/17	LEWIS	ТНС	KUFNER	01992
0010	01/06/17	LEWIS	THC	KUFNER	01992
0011	01/06/17	LEWIS	THC	KUFNER	01992
0012	01/06/17	LEWIS	THC	KUFNER	01991
0013	01/06/17	LEWIS	THC	KUFNER	01992
0014	01/06/17	LEWIS	THC	KUFNER	01992
0015	01/06/17	LEWIS	THC	KUFNER	01992
0016	01/06/17	LEWIS	THC	KUFNER	01992
0017	01/06/17	LEWIS	THC	KUFNER	01992
0018	12/06/16	LEWIS	THC	EDU	01992
0019	11/02/16	LEWIS	THC	EDU	01991
0020	11/02/16	LEWIS	THC	EDU	LUMBAR EPIDERAL WITH FLURO
0021	02/08/17	LEWIS	THC	EDU	01992

0022	02/09/17	LEWIS	THC	EDU	01992
0023	12/06/16	LEWIS	THC	EDU	01992
0024	12/06/16	LEWIS	THC	EDU	01991
0025	12/06/16	LEWIS	THC	EDU	50
0026	11/03/16	LEWIS	THC	N/A	64493, 64494, 64495
0027	11/03/16	LEWIS	THC	N/A	01991
0028	11/29/16	LEWIS	THC	EDU	01992
0029	11/29/16	LEWIS	THC	EDU	01992
0030	11/26/16	LEWIS	THC	EDU	01992
0031	11/26/16	LEWIS	THC	EDU .	01992
0032	11/26/16	LEWIS	THC	EDU	77003
0033	11/23/16	LEWIS	THC	EDU	27096
0034	11/23/16	LEWIS	THC	EDU	77003
0035	11/23/16	LEWIS	THC	EDU	27096 (X2)
0036	11/23/16	LEWIS	THC	N/A	77003
0037	11/23/16	LEWIS	THC	EDU	64493, 64494, 64495
0038	11/23/16	LEWIS	THC	EDU	62311
0039	11/23/16	LEWIS	THC	EDU	01992
0040	01/10/17	LEWIS	THC	EDU	01991
0041	01/10/17	LEWIS	THC	EDU	01991
0042	01/10/17	LEWIS	THC	EDU	01992
0043	12/20/16	LEWIS	THC	N/A	01992
0044	01/03/17	LEWIS	THC	EDU	01992
0045	12/20/16	LEWIS	THC	EDU	01991
0046	12/20/16	LEWIS	THC	EDU	01992
0047	12/13/16	LEWIS	THC	EDU	01992

					0.1.	
0048	12/13/16	LEWIS	THC	EDU	019	992
0049	12/8/16	LEWIS	THC	EDU	019	991
0050	12/8/16	LEWIS	THC	EDU	019	992
0051	12/8/16	LEWIS	THC	EDU	01	991
0052	12/06/16	LEWIS	THC	EDU	01	991
0053	12/13/16	LEWIS	THC	EDU	01	992
0054	12/13/16	LEWIS	THC	EDU	01	991
0055	12/13/16	LEWIS	THC	EDU	01	992
0056	01/10/17	LEWIS	THC	EDU	01	992
0057	11/22/16	LEWIS	THC	EDU	01	991
0058	11/17/16	LEWIS	THC	EDU	01	991
0059	11/17/16	LEWIS	THC	BOTHRA	77	003
0060	11/16/16	LEWIS	THC	EDU	99	213
0061	11/07/16	LEWIS	THC	EDU	99	213
0062	11/09/16	LEWIS	THC	EDU	99	213
0063	12/02/16	LEWIS	N/A	EDU	99	213
0064	12/19/16	LEWIS	N/A	EDU	99	213

35. Please see attached **Exhibit C** for approximately 1,700 examples of other suspected fraudulent billing practices. The Co-Relators believe that there may well be other instances of this behavior that has yet to been uncovered, and that the number of occurrences could be substantial.

II FRAUDULENT BILLING FOR DURABLE MEDICAL EQUIPTMENT

- 36. Co-Relators incorporate by reference each and every preceding paragraph as if each was set forth again at length here, sentence for sentence and word for word.
 - 37. Defendants' regularly order Durable Medical Equipment (DME)
- 38. Co-Relators have knowledge that Defendants fraudulently bill and solicit money from the government for unnecessary DME. Such equipment includes back braces and shoulder braces. Each back brace costs the government approximately \$1200 \$1800, while each shoulder brace costs the government approximately \$800.
- 39. Co-Relators have knowledge of Defendants improperly billing for equipment such as shoulder and back braces, when such equipment is unnecessary. For example, Defendants have over 100 new patients per month. Of those, the majority are ordered back braces and/or shoulder braces. Even though the government pays for such equipment through Medicare and Medicaid, some

patients never actually receive those braces, or are not provided the proper equipment and/or services.

- 40. Many of the patients that do actually receive those braces fail to receive proper instruction as to the use of these devices, and some leave the clinic unaware of the purpose. Additionally, there is little or no documentation of the patient's continued use of the device or its effect on the patient's medical condition.
- 41. Co-Relators are aware of the pressures to provide DME, as evidenced by the magnitude of the prescribing practice and the notes left by Dr. Bothra instructing the other doctors to bill for back and shoulder braces.

III. FRAUDULENT BILLING UNDER THE AMBULATORY SURGICAL CENTER FOR PROVIDING SERVCES NOT MEETING PROPER STANDARDS

- 42. Co-Relators incorporate by reference each and every preceding paragraph as if each was set forth again at length here, sentence for sentence and word for word.
- 43. Ambulatory Surgical Centers (ASCs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions for Coverage (CFC) in order to receive Medicare/Medicaid payment.
- 44. Defendants currently have one operating room that is ASC certified. For operations conducted in these operating rooms by certified doctors, Defendants

are able to solicit the government for two types of fees: a facility fee (for operating in an ASC compliant room) and a professional fee (for an ASC certified doctor operating in an ASC compliant room).

- 45. Defendants' current and only ASC certified operating room did not come into existence until December 24, 2015, but it was not ASC certified by the CMS until February of 2017. Prior to receiving this ASC certification however, Defendants were billing the government for services done by ASC certified doctors in non-ASC operating rooms, as if those services were being done by those doctors in facilities that were ASC certified. Defendants would simply bill the government for a professional fee, knowing that CMS will not verify whether those services were rendered in an ASC certified operating room. Co-Relators have knowledge that Defendants did not become ASC certified by the CMS until February 18, 2017, yet throughout 2016 Defendants were fraudulently billing the government for services and representing that those services were done in an ASC operating room.
- 46. Furthermore, Defendants have stated an objective of having two functioning procedure rooms at full capacity, performing up to 50 cases per day in each room, five or more days a week.
- 47. Currently there are two rooms: a procedure room which is not ASC approved, and an operating room which is considered ASC approved. For

operations in the ASC approved room, a doctor can bill for approximately four times the amount than he would have been able to in a non-ASC approved room. However, to maintain status as an ASC approved operating room, there are more regulations that must be adhered to. Such regulations were developed by the Centers for Medicare & Medicaid Services (CMS). Also, the process from admission, to injection, to discharge is much simpler and faster in a non-ASC room as compared to an ASC approved one.

- 48. As observed by the Co-Relators, the policies and procedures set forth for certification as an ASC by CMS were observed and practiced to a large extent only when the clinic approached an inspection. In fact, as demonstrated in **Exhibit D**, on October 18, 2016 Defendants were subject to an unannounced inspection by The Joint Commission (which conducts compliance inspections for CMS) in order to determine whether Defendants' actions were in compliance with ASC regulations. The Joint Commission then issued a 44 page report finding Defendants not in compliance with ASC standards. Although Defendants were more prepared for their next inspection and ultimately received ASC certification, Co-Relators have personal knowledge of Defendants still continuing to violate many of the ASC regulations to this day.
- 49. Furthermore, Co-Relators have personal knowledge of certain CMS standards and procedures that are being disregarded by Defendants, which include

but are not limited to, procedures being performed in the non-ASC-approved operating room, yet Defendants still improperly bill the government for reimbursement by portraying that such services were actually performed in an ASC approved room.

- 50. Another example of procedures being performed by Defendants, while not meeting standards to qualify for billing the government, is seen in the handling and administering of dose vials. CMS requires that only single dose vials be used in the ASC operating room, and that they be used only on a single patient. Multiple dose vials are not to be used, unless such vials are used to fill a syringe with a single vial outside of the operating room, and then brought in (after being properly labelled). Defendants do not adhere to this regulation. Rather, single and multiple vials are commingled in the operating room, and both are used on multiple patients and stored overnight.
- 51. Co-Relators also have knowledge of procedures being done in the non-ASC operating room, but being billed as if such those procedures were actually done in the ASC operating room.
- 52. Co-Relators also have knowledge of other violations of CMS regulations including, but not limited to, 1) failing to properly train and educate staff members and ensure that such members are properly licensed and/or certified to be performing the work that is being administered, 2) failing to properly

examine and maintain the equipment within the facilities so to ensure that such equipment is in good working order, and to determine whether certain environmental and sanitary requirements have been met (see Exhibit E -Equipment Monitoring log, which was discovered on May 10, 2017 as fraudulently filled out for the entire month of May 2017), 3) failing to properly maintain and ensure that the Medical Gas and Oxygen Logs are completed properly as required by CMS for the ASC to exist, 4) failing to complete a comprehensive medical history and physical assessment within 30 days of the date of planned surgery (rather, such assessments have often been completed afterwards), 5) failing to conduct surgical procedures in compliance with the ASC standards set to avoid wrong site/wrong person/wrong procedure errors, 6) failing to secure patient care supplies (as required by CMS), including syringes, needles, and potentially injurious medications, 7) failing to secure access to the operative and recovery area of the facilities, thereby allowing patients unfettered access into the pre and post op areas, 8) failing to appropriately clean between surgical cases, 9) failing to train all surgical staff in the use of emergency equipment, 10) failing to have patients sign informed consent forms in the manner required by CMS, 11) failing to properly train or supervise staff members in compliance with the standards set by CMS for the ASC to exist, and 12) failing to have at least the required minimum nursing staff during, pre, post, and intra operating procedures. As demonstrated in Exhibit **D**, many of these existing violations mirror that which existed in October 2016 when Defendants failed their first inspection.

COUNT I

Federal False Claims Act (31 USC 3729(a)(1)(A))

- 53. Co-Relators incorporate by reference each and every preceding paragraph as if each was set forth again at length here, sentence for sentence and word for word.
- 54. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729. et seq., as amended.
- 55. Defendants knowingly and intentionally submitted, or caused to be presented, claims for payment for services where said claims contained falsity and misrepresentation.
- 57. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.
- 58. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay claims that are fraudulently submitted.
- 59. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at

- trial. Federal health insurance programs have paid many claims that have been fraudulently submitted, which has amounted to millions of dollars illegally induced by Defendant.
- 60. As such, Defendants submitted false claims and violated the False Claims Acts of the United States and are liable for all damages, penalties, fines set forth in those acts, as well as all other applicable relief.

COUNT II

FEDERAL FALSE CLAIMS ACT (31 USC 3729(a)(1)(B)

- 61. Co-Relators incorporate by reference each and every preceding paragraph as if each was set forth again at length here, sentence for sentence and word for word.
- 62. Defendants knowingly and intentionally used or made, or caused to be used or made, false records or statements, i.e. the false certifications and representations, when they submitted claims for payment for that were not properly indicated or documented.
- 63. As such, Defendants submitted false claims and violated the False Claims Acts of the United States and are liable for all damages, penalties, fines set forth in those acts, as well as all other applicable relief.

COUNT III

FEDERAL FALSE CLAIMS ACT (31 USC 3729(a)(1)(G)

- 64. Co-Relators incorporate by reference each and every preceding paragraph as if each was set forth again at length here, sentence for sentence and word for word.
- 65. Defendants knowingly and intentionally used or made, or caused to be used or made, false records or statements, i.e. the false certifications and representations, when they submitted claims for payment for that were not properly indicated or documented.
- 66. As such, Defendants submitted false claims and violated the False Claims Acts of the United States and are liable for all damages, penalties, fines set forth in those acts, as well as all other applicable relief.

COUNT IV

Michigan Medicaid False Claims Act (MCL 400.610a(2))

- 67. Co-Relators incorporate by reference each and every preceding paragraph as if each was set forth again at length here, sentence for sentence and word for word.
- 68. The above actions, omissions, and allegations are all violations of the appropriate sections of the Michigan Medicaid False Claims Act.

69. As such, Defendants submitted false claims and violated the False Claims Acts of the United States and the State of Michigan, and is liable for all damages, penalties, fines set forth in those acts, as well as all other applicable relief.

PRAYER FOR RELIEF

WHEREFORE, Co-Relators Dr. Ronald Kufner, M.D. and Sanjit Jayakar, by and through their attorneys, on behalf of the United States of America and the State of Michigan, respectfully request judgment be entered in their favor against Defendant, including:

- 1) Treble the amount of the United States and the State of Michigan's damages;
- 2) Any and all additional compensation, penalties, damages and relief allowable under the *Qui Tam* provisions of the Federal False Claims Act, being 31 USC 3729 et. seq. and the Michigan Medicaid False Claims Act, being MCL 400.610a;
- 3) Costs, interest and attorney fees;
- 4) Other applicable legal and/or equitable relief that this court deems just and applicable.

Co-Relators respectfully request an applicable percentage of the total award as determined by this Honorable Court to be justified under the circumstances and taking into consideration, among other things, whether the United States or State of Michigan governments intervene in this action.

Respectfully submitted,

AKEEL & VALENTINE, PLC

By: /s/: SHEREEF H. AKEEL

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Dated: May 24, 2017

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

UNITED STATE OF AMERICA) Civil Action No.
Ex. Rel. RONALD KUFNER, M.D. SANJIT JAYAKAR Plaintiffs,) FILED <i>IN CAMERA</i> AND) UNDER SEAL
vs.) FALSE CLAIMS ACT MEDICARE AND MEDICAID FRAUD
THE PAIN CENTER USA, PLLC, INTERVENTIONAL PAIN CENTER, PLLC,) AND RAJENDRA BOTHRA, M.D.) JURY TRIAL DEMANDED
Defendants.	,)

JURY DEMAND

NOW COMES Co-Relators, RONALD KUFNER, M.D. and SANJIT JAYAKAR, by and through their attorneys, Akeel & Valentine, PLC, and hereby demands a trial by Jury of the above-captioned cause of action.

Respectfully submitted,

AKEEL & VALENTINE, PLC

By:/s/: SHEREEF H. AKEEL Shereef H. Akeel (P54345)

> Adam S. Akeel (P81328) Attorneys for Plaintiff

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Dated: May 24, 2017

EXHIBIT A

MEMORANDUM PURSUANT TO 31 U.S.C. §§ 3730(e)(4)(B) and 3730(b)(2) AND PURSUANT TO MCL 400.610(a)(2) DISCLOSING MATERIAL EVIDENCE SUPPORTING FALSE CLAIMS ACT COMPLAINT AGAINST THE PAIN CENTER USA, PLLC, INTERVENTIONAL PAIN CLINIC, PLLC, AND RAJENDRA BATHRA, M.D. BY CO-RELATORS CONFIDENTIAL AND PRIVILEGED

This document is subject to the attorney-client privilege and the attorney work product doctrine and was prepared by attorneys for the Relators in anticipation of litigation. Submission of this document to the United States Government is not and shall not be construed to be a waiver of any privilege or a waiver of any exemption from discovery of this document that otherwise applies.

INTRODUCTION

This document is voluntarily provided to the government pursuant to an action under the False Claims Act, § 31 U.S.C. §§ 3729 et seq and MCL 400.610(a)(2). Submission of this memorandum does not constitute an admission that any of the information upon which Relators' claim is based was publicly disclosed. The anticipated suit involves violations of the Federal and State False Claims Acts by THE PAIN CENTER USA, PLLC ("TPC"), INTERVENTIONAL PAIN CLINIC, PLLC ("IPC"), and RAJENDRA BOTHRA, M.D. ("Dr. Bothra").

The violations of the False Claims Act arise because Defendants knowingly, intentionally, and fraudulently presented false records or statements to the government of the United States in order to solicit large sums of money in Medicare and Medicaid funds. In essence, as will be discussed below, TPC, IPC, and Dr. Bothra engaged (and continue to engage) in a deliberate course of conduct designed to defraud the federal government of millions of dollars.

This case involves an egregious, and systematic, scheme involving false claims presented for payment, and false documents submitted in order to get claims paid. As more fully described below, these claims were submitted to the United States government by the Defendants and are related to their fraudulently solicited Medicare and Medicaid payments. Defendants profited from this abusive scheme by, among other things, 1) improperly billing Medicare and Medicaid for services; 2) improperly billing Medicare and Medicaid under a certified doctor's name, even though the work was done by other doctors ineligible to bill for Medicare and Medicaid; 4) improperly billing for procedures by claiming that such procedures were done in an Ambulatory Surgery Center (ASC) when in reality such procedures were done in an uncertified operating room; 5) improperly billing Medicare and Medicaid for unnecessary back braces, shoulder braces, and other equipment, 6) improperly billing for services that do not meet acceptable standards, and 7) other improper and illegal acts causing false claims to be submitted.

Relators brings this action, individually, and on behalf of the United States of America against Defendants for actual damages, treble damages, and civil penalties arising from Defendants' false statements and false claims in violation of the Civil False Claims Act, 31 U.S.C. § 3729 et seq. Relators also bring this action on behalf of the State of Michigan for such damages pursuant to MCL 400.610(a)(2).

THE PARTIES

I. RELATORS:

Dr. Ronald Kufner is a citizen and a resident of the United States of America. He is the "original source" of this information within the meaning of 31 U.S.C. § 3730(e)(4)(B) and under applicable state laws, but states that to his knowledge the information contained herein concerning Defendants' alleged False Claim Act violations has not been publicly disclosed.

Dr. Kufner is a physician in active practice and is double-boarded in Anesthesiology and Pain Medicine by the American Society of Anesthesiology. He has been practicing for more than 25 years. At all relevant times herein, Dr. Kufner was and is employed by working for Defendants, TPC, IPC, and Dr. Bothra, in some capacity.

Sanjit JayaKar is also a citizen and a resident of the United States of America. He is also the "original source" of this information within the meaning of 31 U.S.C. § 3730(e)(4)(B) and under applicable state laws, but states that to his knowledge the information contained herein concerning Defendants' alleged False Claim Act violations has not been publicly disclosed.

Mr. Jayakar served as the Chief Operating Officer for Defendants where he maintained full oversight of all personnel, all departments, and all processes that occurred within Defendants' facilities. Co-Relator Sanjit JayaKar was employed by Defendants in early 2015, and remained there until he was terminated on December 31, 2016.

II. DEFENDANTS:

Defendant TPC is a professional limited liability company with two offices located at 27423 Van Dyke, Warren, MI 48093, and 22480 Kelly Road, Eastpointe, MI 48201. Defendant TPC is a medical practice that is owned, operated, and/or controlled by Defendant Bothra.

Defendant IPC is a professional limited liability company which is also located at 27423 Van Dyke, Warren, MI 48093. IPC is also a medical practice owned, operated, and/or controlled by Defendant Bothra.

Defendant Rajendra Bothra is a doctor, and a graduate from Rajasthan University in Bikaner, Rajasthan, India, and currently owns, controls, and operates both corporate Defendants, TPC and IPC.

III. DEFENDANTS' FRAUDULENT SCHEMES

a. Fraudulent Billing for Services:

The United States administers the Federal Medicare Program through its agency, The Department of Health and Human Services (DHHS), though The Center of Medicare and Medicaid (CMS). CMS is responsible for administering the Federal Medicare Program and Medicaid payments. Therefore, CMS (and the State of Michigan) have established regulations in which practicing physicians and medical practices must abide by in order to receive Medicare and Medicaid funds from the government. For several years now, Defendants have failed to abide by these regulations, yet fraudulently soliciting Medicare and Medicaid funds from the government by representing compliance with the required regulations.

For example, in order to bill for surgical procedures in the IPC, CMS requires that surgical procedures be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the Ambulatory Surgical Center (ASC) in accordance with approved policies and procedures of the ASC.

Defendants currently employ at least six practicing doctors at the IPC. Of the practicing doctors, and at relative times herein, some of the doctors were/are ASC credentialed which allows them to receive Medicare and Medicaid funds from certain insurers capable of retroactively administering government Medicare and Medicaid funds. These insurers include, Aetna (AE), Blue Cross Complete (BCC), Total Health Care (THC), and Meridian (ME). Several of the other doctors were/are not credentialed and therefore services performed by those doctors should not be used to solicit Medicare and Medicaid funds for services that they render.

Defendant Bothra is responsible for determining how to categorize the services done by the non-credentialed doctors, and Co-Relators have knowledge of Defendant Bothra intentionally and improperly categorizing those services so to fraudulently solicit Medicare and/or Medicaid funds from the government. As such, many of the actual medical treatment that have been performed by those non-credentialed doctors have been attributed and billed in the names of the credentialed doctors, although the latter did not perform the treatment. In other words, Defendants would simply bill for work performed under a credentialed doctor's name, even though such work was actually performed by a non-credentialed doctor. This, in effect, allowed Defendants to fraudulently solicit Medicare and Medicaid funds from the government. (See **Exhibit A** – Pictures showing Defendants' fraudulent attributing of services done by an uncertified doctor, to that of a certified doctor)

For Example, work done by a Dr. Lewis (a non-credentialed doctor), was repeatedly billed under Dr. Kufner's name (credentialed doctor and the Co-Realtor). This was unbeknownst to Dr. Kufner. See examples of fraudulent billings below that Dr. Kufner discovered:

Document ID	Date	Doctor	Health Provider	Billed Under	Treatment 1
0001	12/10/16	LEWIS	THC	KUFNER	01992
0002	12/3/16	LEWIS	THC	KUFNER	01992
0003	12/3/16	LEWIS	THC	KUFNER	01992
0004	12/3/16	LEWIS	THC	KUFNER	01992
0005	12/3/16	LEWIS	THC	KUFNER	01992
0006	01/06/17	LEWIS	THC	KUFNER	01992
0007	01/06/17	LEWIS	THC	KUFNER	01992
0008	01/06/17	LEWIS	THC	KUFNER	01992
0009	01/06/17	LEWIS	THC	KUFNER	01992
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0013	01/06/17	LEWIS	THC	KUFNER	01992
0014	01/06/17	LEWIS	THC	KUFNER	01992
0015	01/06/17	LEWIS	THC	KUFNER	01992
0016	01/06/17	LEWIS	THC	KUFNER	01992
0017	01/06/17	LEWIS	THC	KUFNER	01992
0018	12/06/16	LEWIS	THC	EDU	01992
0019	11/02/16	LEWIS	THC	EDU	01991
0020	11/02/16	LEWIS	THC	EDU	LUMBAR EPIDERAL WITH FLURO
0021	02/08/17	LEWIS	THC	EDU	01992
0022	02/09/17	LEWIS	THC	EDU	01992
0023	12/06/16	LEWIS	THC	EDU	01992
0024	12/06/16	LEWIS	THC	EDU	01991
0025	12/06/16	LEWIS	THC	EDU	50
0026	11/03/16	LEWIS	THC	N/A	64493, 64494, 64495

0027	11/03/16	LEWIS	THC	N/A	01991
0028	11/29/16	LEWIS	THC	EDU	01992
0029	11/29/16	LEWIS	THC	EDU	01992
0030	11/26/16	LEWIS	THC	EDU	01992
0031	11/26/16	LEWIS	THC	EDU	01992
0032	11/26/16	LEWIS	THC	EDU	77003
0033	11/23/16	LEWIS	THC	EDU	27096
0034	11/23/16	LEWIS	THC	EDU	77003
0035	11/23/16	LEWIS	THC	EDU	27096 (X2)
0036	11/23/16	LEWIS	THC	N/A	77003
0037	11/23/16	LEWIS	THC	EDU	64493, 64494, 64495
0038	11/23/16	LEWIS	THC	EDU	62311
0039	11/23/16	LEWIS	THC	EDU	01992
0040	01/10/17	LEWIS	THC	EDU	01991
0041	01/10/17	LEWIS	THC	EDU	01991
0042	01/10/17	LEWIS	THC	EDU	01992
0043	12/20/16	LEWIS	THC	N/A	01992
0044	01/03/17	LEWIS	THC	EDU	01992
0045	12/20/16	LEWIS	THC	EDU	01991
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0050	12/8/16	LEWIS	THC	EDU	01992
0051	12/8/16	LEWIS	THC	EDU	01991
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0055	12/13/16	LEWIS	THC	EDU	01992
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0057	11/22/16	LEWIS	THC	EDU	01991
0058	11/17/16	LEWIS	THC	EDU	01991
0059	11/17/16	LEWIS	THC	BOTHRA	77003
0060	11/16/16	LEWIS	THC	EDU	99213
0061	11/07/16	LEWIS	THC	EDU	99213
0062	11/09/16	LEWIS	THC	EDU	99213
0063	12/02/16	LEWIS	N/A	EDU	99213
0064	12/19/16	LEWIS	N/A	EDU	99213

Please see attached **Exhibit B** for approximately 1,700 examples of the fraudulent billing practices. The Co-Relators believe that there may well be other instances of this behavior that has yet to been uncovered, and that the number of occurrences could be substantial.

Because of this scheme, many of the submission that have been made (and continue to be made) to the government to solicit Medicare and Medicaid funds were and are false and fraudulent.

b. Fraudulent Billing for Durable Medical Equipment:

Defendants provide a wide range of services including allegedly providing Durable Medical Equipment to their patients.

Co-Relators have knowledge that Defendants fraudulently bill and solicit money from the government for unnecessary DME. Such equipment includes back braces and shoulder braces. Each back brace costs the government approximately \$1200 - \$1800, while each shoulder brace costs the government approximately \$800.

Co-Relators have knowledge of Defendants improperly billing for equipment such as shoulder and back braces, when such equipment is unnecessary. For example, Defendants have over 100 new patients per month. Of those, the majority are ordered back braces and/or shoulder braces. Even though the government pays for such equipment through Medicare and Medicaid, some patients never actually receive those braces.

Many of the patients that do actually receive those braces fail to receive proper instruction as to the use of these devices, and some leave the clinic unaware of the purpose.

Additionally, there is little or no documentation of the patient's continued use of the device or its effect on the patient's medical condition.

Co-Relators are aware of the pressures to provide DME, as evidenced by the magnitude of the prescribing practice and the notes left by Dr. Bothra instructing the other doctors to bill for back and shoulder braces.

Defendants have been providing DME services for approximately 6 years now. Defendants have made a substantial amount of income by using their DME privileges to fraudulently bill the government and solicit Medicare and Medicaid funds. Such a scheme continues today.

c. <u>Fraudulent Billing Under the Ambulatory Surgical Center for Providing Services Not Meeting Proper Standards:</u>

Ambulatory Surgical Centers (ASCs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions for Coverage (CfC) in order to receive Medicare/Medicaid payment.

Defendants currently have one operating room that is ASC certified. For operations conducted in these operating rooms by certified doctors, Defendants are able to solicit the government for two types of fees: a facility fee (for operating in an ASC compliant room) and a professional fee (for an ASC certified doctor operating in an ASC compliant room).

Defendants' current and only ASC certified operating room did not come into existence until December 24, 2015, but it was not ASC certified by the CMS until February of 2017. Prior to receiving this ASC certification however, Defendants were billing the government for services done by ASC certified doctors in non-ASC operating rooms, as if those services were being done by those doctors in facilities that were ASC certified. Defendants would simply bill the government for a professional fee, knowing that CMS will not verify whether those services were rendered in an ASC certified operating room. Co-Relators have knowledge that Defendants did not become ASC certified by the CMS until February 18, 2017, yet throughout 2016 Defendants were fraudulently billing the government for services and representing that those services were done in an ASC operating room.

Furthermore, Defendants have stated an objective of having two functioning operating rooms at full capacity, performing up to 50 cases per day in each room, five or more days a week.

Currently there are two rooms: a procedure room which is not ASC approved, and an operating room which is considered ASC approved. For operations in the ASC approved room, a doctor can bill for approximately four times the amount than he would have been able to in a non-ASC approved room. However, to maintain status as an ASC approved operating room,

there are more regulations that must be adhered to. Such regulations were developed by the Centers for Medicare & Medicaid Services (CMS). Also, the process from admission, to injection, to discharge is much simpler and faster in a non-ASC room as compared to an ASC approved one.

As observed by the Co-Relators, the policies and procedures set forth for certification as an ASC by CMS were observed and practiced to a large extent only when the clinic approached an inspection. In fact, as demonstrated in **Exhibit C**, on October 18, 2016 Defendants were subject to an unannounced inspection by The Joint Commission (which conducts compliance inspections for CMS) in order to determine whether Defendants' actions were in compliance with ASC regulations. The Joint Commission then issued a 44 page report finding Defendants not in compliance with ASC standards. Although Defendants were more prepared for their next inspection and ultimately received ASC certification, Co-Relators have personal knowledge of Defendants still continuing to violate many of the ASC regulations to this day.

Furthermore, Co-Relators have personal knowledge of certain CMS standards and procedures that are being disregarded by Defendants, which include but are not limited to, procedures being performed in the non-ASC-approved operating room, yet Defendants still improperly bill the government for reimbursement by portraying that such services were actually performed in an ASC approved room. In other words, Defendants intentionally bill the government for a "facility fee", representing that certain services were done in an ASC certified operating room, when in reality, those services were done in a non-ASC certified room and therefore are not entitled to receive a "facility fee".

Another example of procedures being performed by Defendants, while not meeting standards to qualify for billing the government, is seen in the handling and administering of dose vials. CMS requires that only single dose vials be used in the ASC operating room, and that they be used only on a single patient. Multiple dose vials are not to be used, unless such vials are used to fill a syringe with a single vial outside of the operating room, and then brought in (after being properly labelled). Like many other regulations, Defendants do not adhere to this. Rather, single and multiple vials are commingled in the operating room, and both are used on multiple patients and stored overnight.

Co-Relators also have knowledge of other violations of CMS regulations including, but not limited to, 1) failing to properly train and educate staff members and ensure that such members are properly licensed and/or certified to be performing the work that is being administered, 2) failing to properly examine and maintain the equipment within the facilities so to ensure that such equipment is in good working order, and to determine whether certain environmental and sanitary requirements have been met (see **Exhibit D** – Equipment Monitoring log, which was discovered on May 10, 2017 as fraudulently filled out for the entire month of May 2017), 3) failing to properly maintain and ensure that the Medical Gas and Oxygen Logs are completed properly as required by CMS for the ASC to exist, 4) failing to complete a comprehensive medical history and physical assessment within 30 days of the date of planned surgery (rather, such assessments have often been completed afterwards), 5) failing to conduct

surgical procedures in compliance with the ASC standards set to avoid wrong site/wrong person/wrong procedure errors, 6) failing to secure patient care supplies (as required by CMS), including syringes, needles, and potentially injurious medications, 7) failing to secure access to the operative and recovery area of the facilities, thereby allowing patients unfettered access into the pre and post op areas, 8) failing to appropriately clean between surgical cases, 9) failing to train all surgical staff in the use of emergency equipment, 10) failing to have patients sign informed consent forms in the manner required by CMS, 11) failing to properly train or supervise staff members in compliance with the standards set by CMS for the ASC to exist, and 12) failing to have at least the required minimum nursing staff during, pre, post, and intra operating procedures. As demonstrated in **Exhibit C**, many of these existing violations mirror that which existed in October 2016 when Defendants failed their first inspection.

V. CONCLUSION

Even though Defendants know that federal and state Medicare and Medicaid laws and regulations require all forms and requests for payments submitted to the respective governmental departments to be truthful, accurate, and complete, Defendants have intentionally disregarded this obligation, but instead have engaged in a calculated scheme to defraud the United States Government and State of Michigan out of millions of dollar. As such, Defendants are liable for treble the amount of the United States and the State of Michigan's damages, including any other relief allowable under the *Qui Tam* provisions of the Federal False Claims Act, being 31 USC 3729 et. seq, and the Michigan Medicaid False Claims Act, being MCL 400.610a.

Respectfully submitted,

AKEEL & VALENTINE, PLC

s/: Shereef Akeel

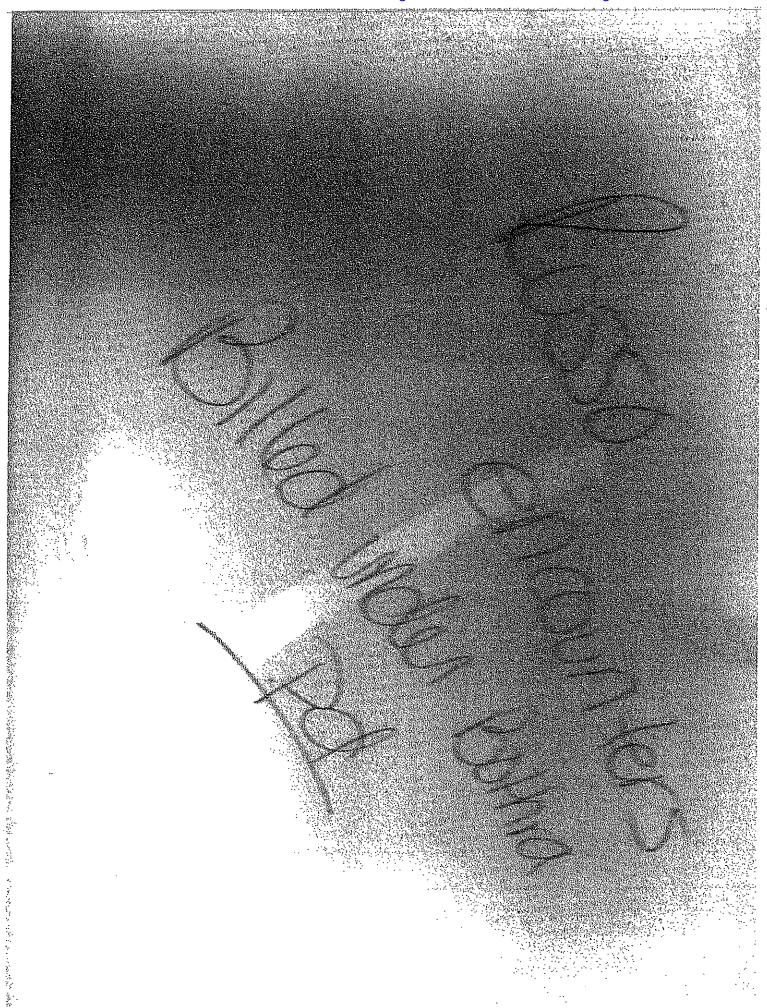
Shereef H. Akeel, Esq. P54345 Adam S. Akeel, Esq. P83128 Attorneys for Plaintiff 888 West Big Beaver Road, Suite 910 Troy, MI 48084-4736

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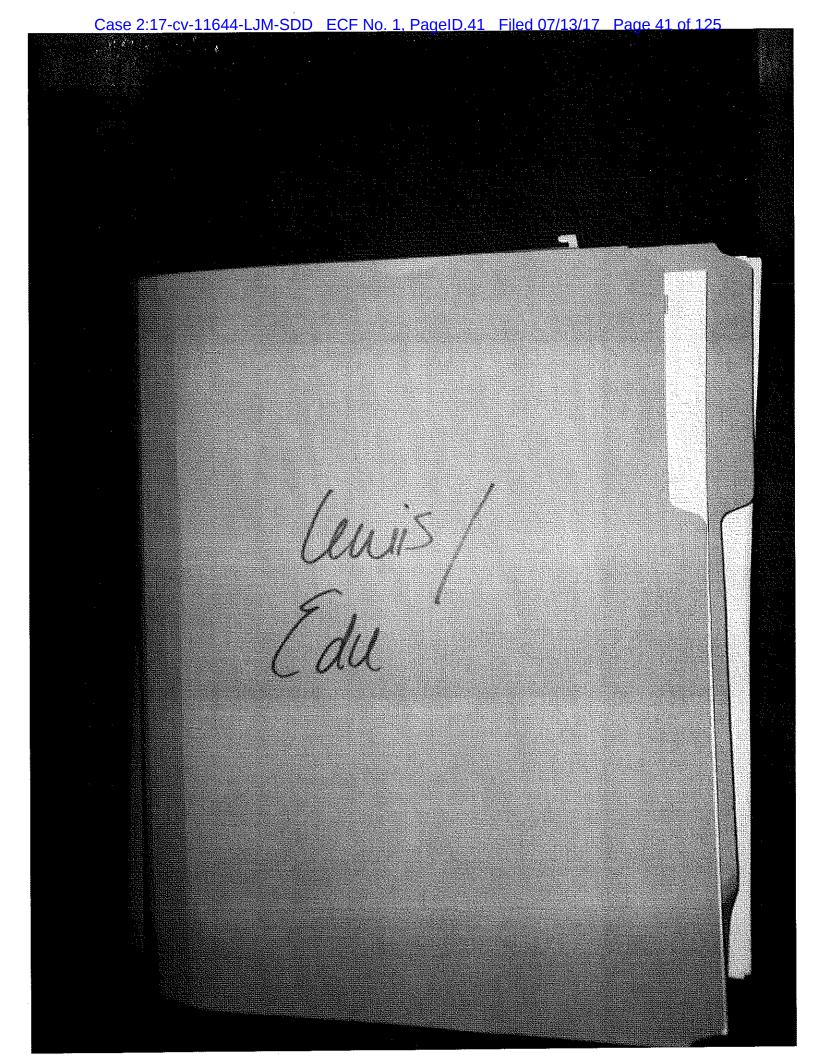
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EXHIBIT B



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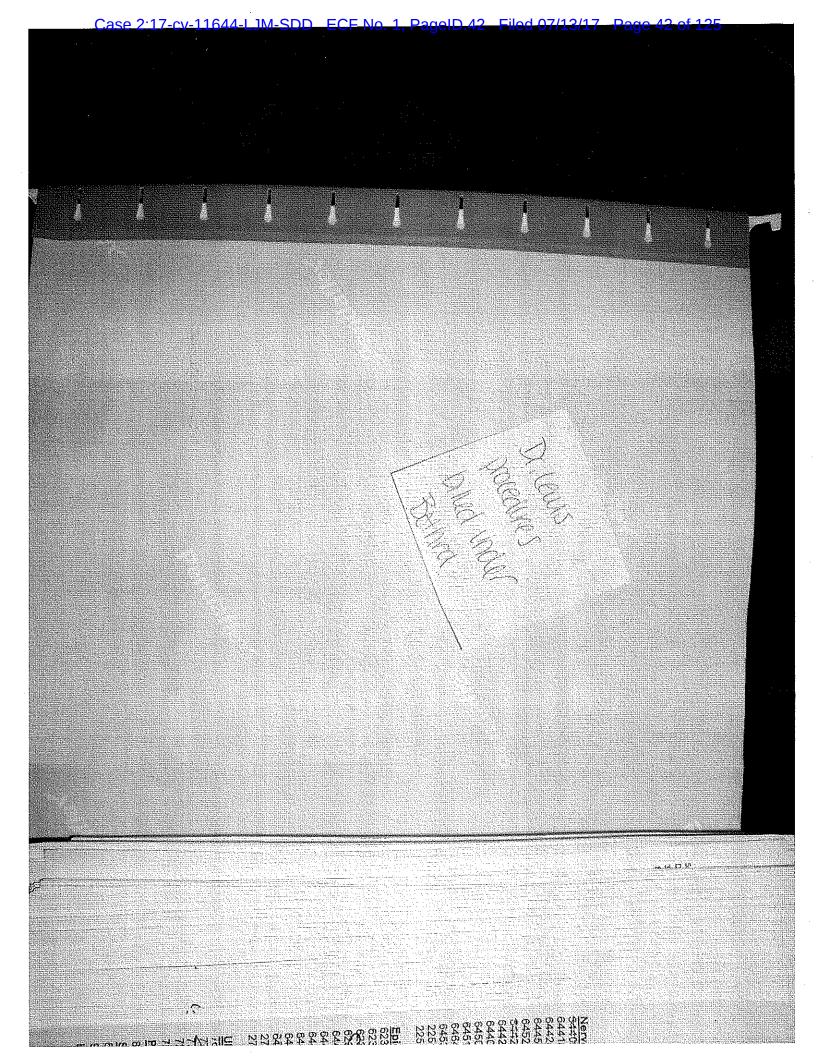


EXHIBIT C

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Carre	BOTHRA (NOT EXPLICIT)	ROTHRA (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT	BOTHRA (NOT EXPLICIT	BOTHRA (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT	BOTHRA (NOT EXPLICIT)	BOTHKA (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT)	SOUTHER (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT)	BOTHRA	BOTHRA (NOT EXPLICIT)	BOTHRA (NOT EXPLICIT)	BOTHPA (NOT EXPLICIT)	EDU	BOTHRA (NOT EXPLICIT)	BOTHRA (NO	BOTHRA (NOT EXPLICIT)	BOTHRA (NO	BOLING (NOT EXPECT)	BOTHRA (NOT EXPLICIT)																											
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	RUSSO	CSSIL	RUSSO	XUSSC P. 1860	KUSSO BUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	XU350	RUSSO	0803	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	0050	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	KUSSO	RUSSO	RUSSO	RUSSO	RUSSO	2000	RUSSO								
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;	80101	80101	80101			13301	80101	99070	80101	20,000	80101		9850	4000A	80101			80101		;	80101			0	80101	80101	13301. 86161	TOTO8		80101	1	13301		80101			99070	80101			SO	-		80101	80101	70	80101	80101	80101	19301
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	BCCOM		BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM .	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM/INID:	NCO III	BCCCM MCCCM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM	BCCOM		BCCOM
	RUSSO	CSSILE	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	KUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	KUSSO	KUSSO	CSSIA	RUSSO	RUSSO	KUFNER	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	RUSSO	CSSUR	RUSSO						
	1007	8001	010	1011	1012	1013	1014	1016	1017	1018	1019	1020	1021	1022	1024	1025	1026	1027	1028	1029	1030	1031	1032	1033	1034	1035	1036	1037	1038	1040	1041	1042	1043	1044	1045	1046	1047	1049	1050	1051	1052	1053	1054	1055	1056	1057	1058	1059	1060	1062

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80101	80101 99070 J3301 80101	80101 99070 99070 13801 13801 99070 99070 99070 99070 99070 99070 99070 99070 99070	J3301 J3301 80101 6450 80101 80101 80101 80101 80101 80101
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13301		02066	80101				ROIOI		80101	80101		80101	99070	99070	80101	0/066		1000		80101				80101				80101	99070	0/088	0/066	0/085	-			64635,64636 (X2)	77003	50	77003	64635,64636 (X3)	20611	02066	13301	77003	100077	5000	20	77003	77003
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EXHIBIT D



Interventional Pain Center PLLC 27423 Van DykeSuite B Warren, MI 48093

Organization Identification Number: 596448

Initial Unannounced Full Event: 10/18/2016 - 10/19/2016

Report Contents

Executive Summary

Requirements for Improvement

Observations noted within the Requirements for Improvement (RFI) section require follow up through the Evidence of Standards Compliance (ESC) process. The timeframe assigned for completion is due in either 45 or 60 days, depending upon whether the observation was noted within a direct or indirect impact standard. (*Please Note: if your survey event resulted in a Preliminary Denial of Accreditation status, your timeframe for ESC completion will be 45 days.*) The identified timeframes of submission for each observation are found within the Requirements for Improvement Summary portion of the final onsite survey report. If a follow-up survey is required, the unannounced visit will focus on the requirements for improvement although other areas, if observed, could still become findings. The time frame for performing the unannounced follow-up visit is dependent on the scope and severity of the issues identified within the Requirements for Improvement.

Opportunities for Improvement

Observations noted within the Opportunities for Improvement (OFI) section of the report represent single instances of non-compliance noted under a C category Element of Performance. Although these observations do not require official follow up through the Evidence of Standards Compliance (ESC) process, they are included to provide your organization with a robust analysis of all instances of non-compliance noted during survey.

Page 2 of 44

Executive Summary

<u>Program(s)</u>
Ambulatory Health Care Accreditation

<u>Survey Date(s)</u> 10/18/2016-10/19/2016

As a result of the survey conducted on the above date(s), the following survey findings have been identified. Your official report will be posted to your organization's confidential extranet site. It will contain specific follow-up instructions regarding your survey findings.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

Page 3 of 44

Requirements for Improvement - Summary

Observations noted within the Requirements for Improvement (RFI) section require follow up through the Evidence of Standards Compliance (ESC) process. The timeframe assigned for completion is due in either 45 or 60 days, depending upon whether the observation was noted within a direct or indirect impact standard. (*Please Note: if your survey event resulted in a Preliminary Denial of Accreditation status, your timeframe for ESC completion will be 45 days.*) The identified timeframes of submission for each observation are found within the Requirements for Improvement Summary portion of the final onsite survey report. If a follow-up survey is required, the unannounced visit will focus on the requirements for improvement although other areas, if observed, could still become findings. The time frame for performing the unannounced follow-up visit is dependent on the scope and severity of the issues identified within the Requirements for Improvement.

DIRECT Impact Standards:

	4 5 441	
Program:	Ambulatory Health Care Accreditation Program	
Standards:	EC.02.04.03	EP4
	EC.02.05.03	EP10
	IC.02.02.01	EP2
	LD.04.01.01	EP15
	MM.01.02.01	EP1,EP2
	PC.03.01.03	EP14,EP15
	PC.03.01.05	EP1
	PC.03.01.07	EP1,EP5
	UP.01.03.01	EP5
	WT.03.01.01	EP5

INDIRECT Impact Standards:

Program:	Ambulatory Health Care Accreditation Program	
Standards:	EC.02.03.03	EP2
	EC.02.03.05	EP5,EP15
	EC.02.05.07	EP1
	EC.02.06.01	EP1,EP13

Organization Identification Number: 596448

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.81 Filed 07/13/17 Page 81 of 125 The Joint Commission

INDIRECT Impact Standards:

	HR.01.04.01	EP5
	HR.02.01.03	EP3,EP16,EP24
	HR.02.02.01	EP1,EP2,EP3,EP4,EP5
	IC.01.01.01	EP3,EP5
	IC.01.05.01	EP1,EP9
	LD.01.03.01	EP2
	LS.03.01.30	EP5
	MM.01.01.03	EP1,EP2
	NPSG.07.01.01	EP2
	RI.01.01.01	EP2
	RI.01.05.01	EP1
	WT.01.01.01	EP2
	WT.05.01.01	EP3
1	•	

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.82 Filed 07/13/17 Page 82 of 125

The Joint Commission Summary of CMS Findings

CFC:

\$416.41

Tag: Q-0040

Deficiency: Condition

Corresponds to: AHC - LD.01.03.01/EP2

Text:

§416.41 Condition for Coverage: Governing Body and Management

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that the facility policies and programs are administered so as to provide quality healthcare in a safe environment, and develops

and maintains a disaster preparedness plan.

CFC:

§416.42

Tag: Q-0060

Deficiency: Standard

Corresponds to: AHC

Text:

§416.42 Condition for Coverage: Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance

with approved policies and procedures of the ASC.

CFC Standard	Tag	Corresponds to	Deficiency
§416.42(a)(2)	Q-0062	AHC - PC.03.01.07/EP1, EP5	Standard

CFC:

§416.44

Tag: Q-0100

Deficiency: Condition

Corresponds to: AHC - EC.02.06.01/EP1

Text:

§416.44 Conditions for Coverage: Environment

The ASC must have a safe and sanitary environment, properly constructed, equipped,

and maintained to protect the health and safety of patients.

CFC Standard	Tag	Corresponds to	Deficiency
§416.44(a)	Q-0101	AHC - EC.02.04.03/EP4, EC.02.05.07/EP1	Standard
§416.44(b)	Q-0104	AHC - EC.02.03.05/EP5, EP15	Standard
§416.44(a)(1)	Q-0101 .	AHC - EC.02.06.01/EP1, EP13	Standard
	Q-0104	AHC - EC.02.05.03/EP10, LS.03.01.30/EP5	Standard

CFC:

§416.45

Tag: Q-0120

Deficiency: Standard

Corresponds to: AHC

Text:

§416.45 Condition for Coverage: Medical Staff

The medical staff of the ASC must be accountable to the governing body.

CFC Standard	T	Corresponds to	Deficiency
§416.45(c)	Q-0123	AHC - HR.02.01.03/EP24, EP3, EP16	Standard

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.83 Filed 07/13/17 Page 83 of 125.

The Joint Commission Summary of CMS Findings

CFC:

§416.49

Tag: Q-0200

Deficiency: Standard

Corresponds to: AHC

Text:

§416.49 Condition for Coverage: Laboratory and Radiology Services.

CFC Standard	Tag	Corresponds to	Deficiency
§416.49(a)	Q-0201	AHC - LD.04.01.01/EP15	Standard

CFC:

\$416.51

Tag: Q-0240

Deficiency: Condition

Corresponds to: AHC - IC.01.01.01/EP3

Text:

§416.51 Condition for Coverage - Infection control

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

CFC Standard	Tag	Corresponds to	Deficiency
§416.51(a)	Q-0241	AHC - IC.02.02.01/EP2	Standard
§416.51(b)	Q-0242	AHC - IC.01.05.01/EP9	Standard
§416.51(b)(1)	Q-0243	AHC - IC.01.01.01/EP5	Standard
§416.51(b)(3)	Q-0245	AHC - IC.01.05.01/EP1	Standard

CFC:

§416.50

Tag: Q-0219

Deficiency: Standard

Corresponds to: AHC - RI.01.01.01/EP2

Text:

§416.50 Condition for coverage - Patient Rights

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

CFC Standard	Tag	Corresponds to	Deficiency
§416.50(c)(1)	Q-0224	AHC - RI.01.05.01/EP1	Standard

CFC:

Text:

§416.52

Tag: Q-0260

Deficiency: Standard

Corresponds to: AHC

§416.52 Conditions for Coverage: Patient Admission, Assessment and Discharge

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

CFC Standard	Tag	Corresponds to	Deficiency
§416.52(a)(1)	Q-0261	AHC - PC.03.01.03/EP14	Standard
§416.52(a)(2)	Q-0262	AHC - PC.03.01.03/EP15	Standard

Requirements for Improvement - Detail

Chapter:

Environment of Care

Program:

Ambulatory Health Care Accreditation

Standard:

EC.02.03.03

Standard Text:

The organization conducts fire drills.

Element(s) of Performance:

2. The organization conducts fire drills every 12 months from the date of the last drill in each area that is defined as a business occupancy by the Life Safety Code and in which care, treatment, or services are provided, or quarterly for ambulatory surgical centers seeking accreditation for Medicare certification.

Note 1: In leased or rented facilities, drills need be conducted only in areas of the building that the organization occupies.

Note 2: In sites that are used on average 70 hours or less per month, the organization may choose either to review the fire response plan or to conduct a fire drill every 12 months. This note does not apply to ambulatory surgical centers that elect to use The Joint Commission deemed status option.

Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 2

Observed in Document Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI)

The organization didn't present fire drill results for the period of April 2016 - September 2016.

Chapter:

Environment of Care

Program:

Ambulatory Health Care Accreditation

Standard:

EC.02.03.05

Page 8 of 44

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Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.85 Filed 07/13/17 Page 85 of 125

The Joint Commission

Standard Text:

The organization maintains fire safety equipment and fire safety building features. Note: This standard does not require organizations to have the types of fire safety equipment and building features described below. However, if these types of equipment or features exist within the building, then the following maintenance, testing, and inspection requirements apply.

Element(s) of Performance:

5. Every quarter, the organization tests fire alarm equipment for notifying off-site fire responders. The completion date of the tests is documented. Note: For additional guidance on performing tests, see NFPA 72, 1999 edition (Table 7-3.2).



Scoring Category: A

Score:

Insufficient Compliance

15. At least monthly, the organization inspects portable fire extinguishers. The completion dates of the inspections are documented.

Note 1: There are many ways to document the inspections, such as using bar-coding equipment, using check marks on a tag, or using an inventory. Note 2: Inspections involve a visual check for the presence and correct type of extinguisher, broken parts, full charge; and ease of access.

Note 3: For additional guidance on inspection of fire extinguishers, see NFPA 10, Standard for Portable Fire Extinguishers, 1998 edition (Sections 1-6, 4-3, and 4-4).

Scoring Category: C

Score:

Partial Compliance

Observation(s):

§416.44(b) - (Q-0104) - §416.44(b) Standard: Safety From Fire This Standard is NOT MET as evidenced by:

Observed in Document Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

For the period of April 2016 - September 2016, the organization didn't present test results for the fire alarm

equipment for notifying off-site fire responders.

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.86 Filed 07/13/17 Page 86 of 125

The Joint Commission

EP 15

§416.44(b) - (Q-0104) - §416.44(b) Standard: Safety From Fire

This Standard is NOT MET as evidenced by:

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for

the Ambulatory Surgical Center deemed service.

In 2 of 2 fire extinguisher checks, the organization didn't record inspection results for the period of April 2016 - September 2016. The extinguishers were located in the waiting room and patient preparation area y chedi

respectively.

Chapter:

Environment of Care

Program:

Ambulatory Health Care Accreditation

Standard:

EC.02.04.03

Standard Text:

The organization inspects, tests, and maintains medical equipment

Element(s) of Performance:

4. The organization conducts performance testing of and maintains all sterilizers. These activities are documented. (See also IC.02.02.01, EP 2)

Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

§416.44(a) - (Q-0101) - §416.44 Standard: Physical Environment

(a) The ASC must provide a functional and sanitary environment for the provision of surgical services. This Standard is NOT MET as evidenced by:

Observed in Infection Control System Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

The weekly maintenance of the autoclave as per the manufacturer's guidelines has not been documented as completed.

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

The monthly maintenance of the autoclave as per the manufacturer's guidelines has not been documented

as completed

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.87 Filed 07/13/17 Page 87 of 125 . The Joint Commission

Chapter:

Environment of Care

Program:

Ambulatory Health Care Accreditation

Standard:

EC.02.05.03

Standard Text:

The organization has a reliable emergency electrical power source.

Element(s) of Performance:

10. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: For facilities that were constructed, had a change in occupancy type, or have undergone an electrical system upgrade since 1983, the organization has a Type I or Type 3 essential electrical systems (EES) in accordance with NFPA 99, 1999 edition.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 10

§416.44(b)(1) - (Q-0104) - (1) Except as otherwise provided in this section, the ASC must meet the provision applicable to the ambulatory Healthcare Center of the 2000 edition of the Life Safety code of the National Fire protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Recourse Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information o the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federalregister/code_of_federal_regulations/lbr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, III) site for the Ambulatory Surgical Center deemed service.

The organization didn't have a battery back-up system to supply power to emergency lighting, patient

equipment and monitors.

Chapter:

Environment of Care

Program:

Ambulatory Health Care Accreditation

Standard:

EC.02.05.07

Standard Text:

The organization inspects, tests, and maintains emergency power systems. Note: This standard does not require organizations to have the types of emergency power equipment discussed below. However, if these types of equipment exist within the building, then the following maintenance, testing, and inspection requirements apply.

Element(s) of Performance:

1. At least monthly, the organization performs a functional test of battery-powered lights required for egress for a minimum duration of 30 seconds. The completion date of the tests is documented.



Scoring Category: C

Score:

Insufficient Compliance

Observation(s):

EP 1 §416.44(a) - (Q-0101) - §416.44 Standard: Physical Environment

(a) The ASC must provide a functional and sanitary environment for the provision of surgical services. This Standard is NOT MET as evidenced by:

Observed in Document Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service. In 4 of 4 battery-powered lights, the organization didn't present monthly inspection results.

second de every month.

Chapter:

Environment of Care

Program:

Ambulatory Health Care Accreditation

Standard:

EC.02.06.01

Standard Text:

The organization establishes and maintains a safe, functional environment.

Element(s) of Performance:

1. Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, or services provided.



Scoring Category: C

Score:

Partial Compliance

ase 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.89 Filed 07/13/17 Page 89 of 125 The Joint Commission

13. The organization maintains ventilation, temperature, and humidity levels suitable for the care, treatment, or services provided. (See also EC.02.05.01, EP 6)



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 1

§416.44 - (Q-0100) - §416.44 Condition for Coverage: Environment

This Condition is NOT MET as evidenced by:

§416.44(a)(1) - (Q-0101) - (1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, IVII) site for the Ambulatory Surgical Center deemed service.

There was an in-use O2 E-cylinder tank stored with the full O2 E-cylinder tanks.

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

There were office supplies stored within 3 feet of sub-electrical panel LPF (correct).

EP 13

§416.44(a)(1) - (Q-0101) - (1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in

This Standard is NOT MET as evidenced by:

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

The organization did not present temperature and humidity logs for the wrapped sterile instruments stored Humidaly monitor

in procedure room #2.

304-604 hunding

Chapter:

Human Resources

Program:

Ambulatory Health Care Accreditation

Standard:

HR.01.04.01

Standard Text:

The organization provides orientation to staff.

Element(s) of Performance:

5. The organization orients staff on the following: Sensitivity to cultural diversity based on their job duties and responsibilities. Completion of this orientation is documented.



Scoring Category: C

Score:

Insufficient Compliance

Observation(s):

EP5

Observed in HR File Review at Interventional Pain Center PLLC (27423 Van Dyke, Suité B, Warren, MI) site. In 7 of 7 HR files reviewed, it was noted that documentation of orientation to sensitivity to cultural diversity based on their job duties and responsibilities was not evident in the personnel files.

Chapter:

Human Resources

Program:

Ambulatory Health Care Accreditation

Standard:

HR.02.01.03

Standard Text:

The organization grants initial, renewed, or revised clinical privileges to individuals

who are permitted by law and the organization to practice independently.

Element(s) of Performance:

3. Before granting initial or revised privileges, the organization uses primary sources when documenting training specific to the privileges requested. (See also PC.03.01.01, EP 1) Note 1: The verification of relevant training informs the organization of the licensed independent practitioner's clinical knowledge and skill set. . Verification must be obtained from the primary source of the specific credential. Primary sources include the specialty certifying boards approved by the American Dental Association for a dentist's board certification, letters from professional schools (for example, medical, dental, nursing) and letters from postgraduate education or postdoctoral programs for completion of training. Designated equivalent sources include, but are not limited to, the following:

- The American Medical Association (AMA)
Physician Masterfile for verification of a physician's
U.S. and Puerto Rico medical school graduation
and residency completion

 The American Board of Medical Specialties (ABMS) for verification of a physician's board certification

- The Educational Commission for Foreign Medical Graduates (ECFMG) for verification of a physician's graduation from a foreign medical school - The American Osteopathic Association (AOA) Physician Database for predoctoral education accredited by the AOA Bureau of Professional Education, postdoctoral education approved by the AOA Council on Postdoctoral Training, and

Osteopathic Specialty Board Certification
- The Federation of State Medical Boards (FSMB)
for all actions against a physician's medical license
- The American Academy of Physician Assistants
(AAPA) Profile for physician assistant education,
provided through the AMA Physician Profile Service
(https://profiles.ama-assn.org/amaprofiles/)
Note 2: A primary source of verified information may
designate to an agency the role of communicating
credentials information. The designated agency
then becomes acceptable to be used as a primary
source.

Note 3: An external organization (for example, a credentials verification organization [CVO]) or a Joint Commission—accredited health care organization functioning as a CVO may be used to collect credentialing information. Both of these organizations must meet the CVO guidelines listed in the Glossary.

Note 4: When it is not possible to obtain information from the primary source, reliable secondary sources may be used. A reliable secondary source could be another health care organization that has documented primary source verification of the applicant's credentials.

Page 15 of 44

Scoring Category: A

Score:

Insufficient Compliance

16. Before granting initial, renewed, or revised privileges to a licensed independent practitioner, leadership evaluates the following: Information from the National Practitioner Data Bank.

Scoring Category: A

Score:

Insufficient Compliance

24. The organization notifies the requesting practitioner about the decision to grant, renew, or deny requested privileges. The notification may be in either written or electronic format.



Scoring Category: C

Score:

Insufficient Compliance

Observation(s):

EP 3 §416.45(c) - (Q-0123) - §416.45(c) Standard: Other Practitioners

If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. This Standard is NOT MET as evidenced by:

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.
In 3 of 3 medical staff/credentialing files reviewed, the <u>primary source documentation of training was Not compiled in the credentialing file before the privileges were granted</u>

EP 16 §416.45(c) - (Q-0123) - §416.45(c) Standard: Other Practitioners

If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. This Standard is NOT MET as evidenced by:

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

In 3 of 3 medical staff/credentialing files reviewed, it was noted that the information from the National Practitioner Data Bank was not reviewed before the privileges were granted.

EP 24

§416.45(c) - (Q-0123) - §416.45(c) Standard: Other Practitioners

If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. This Standard is NOT MET as evidenced by:

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, NII) site for the Ambulatory Surgical Center deemed service. In 3 of 3 medical staff/credentialing files reviewed, it was noted that the organization did not notify the practitioner about the decision to grant the requested privileges.

Chapter:

Human Resources

Program:

Ambulatory Health Care Accreditation

Standard:

HR.02.02.01

Standard Text:

The organization provides orientation to licensed independent practitioners.

Element(s) of Performance:

1. The organization determines the key safety content of orientation provided to licensed independent practitioners.

Note: Key safety content may include specific processes and procedures related to the provision of care, the environment of care, and infection control.

Scoring Category: A

Score:

Insufficient Compliance

2. The organization orients its licensed independent practitioners to key safety content before they provide care, treatment, or services. Completion of this orientation is documented.

Scoring Category: C

Score:

Insufficient Compliance

3. The organization orients licensed independent practitioners on the following: Relevant policies and procedures. Completion of this orientation is

documented.

Scoring Category: C

Score:

Insufficient Compliance

4. The organization orients licensed independent practitioners on the following: Their specific responsibilities, including those related to infection prevention and control and assessing and managing pain. Completion of this orientation is documented. (See also IC.01.05.01, EP 6; RI.01.01.01, EP 8)



Scoring Category: C

Score:

Insufficient Compliance

5. The organization orients licensed independent practitioners on the following: Sensitivity to cultural diversity based on their specific responsibilities. Completion of this orientation is documented.



Scoring Category: C

Score:

Insufficient Compliance

Observation(s):

EP₁

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B,

In 3 of 3 medical staff/credentialing files reviewed, after review of the organization's documents and administration it was determined that no key safety content of orientation for the licensed independent practitioners had been formulated.

EP 2

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B,

In 3 of 3 medical staff/credentialing files reviewed, it was noted that completion of orientation to key safety content before they provide care, treatment, or services is not documented in the credentialing files.

EP3

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B,

In 3 of 3 medical staff/credentialing files reviewed, it was noted that completion of orientation to relevant policies and procedures before they provide care, treatment, or services is not documented in the credentialing files.

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.95 Filed 07/13/17 Page 95 of 125

The Joint Commission

EP4

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site.

In 3 of 3 medical staff/credentialing files reviewed, it was noted that completion of orientation to their specific responsibilities, including those related to infection prevention and control and assessing and managing pain before they provide care, treatment, or services is not documented in the credentialing files.

EP 5

Observed in Credentialing and Privileging at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site.

In 3 of 3 medical staff/credentialing files reviewed, it was noted that completion of orientation to sensitivity to cultural diversity based on their specific responsibilities before they provide care, treatment, or services is not documented in the credentialing files.

Chapter:

Infection Prevention and Control

Program:

Ambulatory Health Care Accreditation

Standard:

IC.01.01.01

Standard Text:

The organization identifies the individual(s) responsible for infection prevention and

control.

Element(s) of Performance:

3. The organization assigns responsibility for the management of infection prevention and control activities. (See also HR.01.02.01, EP 1; LD.03.06.01, EP 3)



Scoring Category: A

Score:

Insufficient Compliance

5. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The infection control program is under the direction of a designated and qualified professional who has training in infection control.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 3

§416.51 - (Q-0240) - §416.51 Condition for Coverage; Infection Control

This Condition is NOT MET as evidenced by:

Observed in HR File Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site

for the Ambulatory Surgical Center deemed service.

Upon review of the nurse's personnel file that was designated as the infection control nurse, it was noted that the organization did not assign responsibility for the management of infection prevention and control activities.

EP 5

§416.51(b)(1) - (Q-0243) - (1) Under the direction of a designated and qualified professional who has training in infection control;

This Standard is NOT MET as evidenced by:

Observed in HR File Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

It was noted that the nurse has not had training in infection control.

Chapter:

Infection Prevention and Control

Program:

Ambulatory Health Care Accreditation

Standard:

IC.01.05.01

Standard Text:

The organization plans for preventing and controlling infections.

Element(s) of Performance:

1. When developing infection prevention and control activities, the organization uses evidence-based national guidelines or, in the absence of such guidelines, expert consensus. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The organization considers, selects, and implements nationally recognized infection control program guidelines.

Scoring Category: A

Score:

Insufficient Compliance

9. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The organization plans infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection and communicable diseases. These activities are documented.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 1 §416.51(b)(3) - (Q-0245) - (3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

This Standard is NOT MET as evidenced by:

Observed in Infection Control System Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

The organization did use evidence-based national guidelines white developing infection prevention and quede lives

control activities.

§416.51(b) - (Q-0242) - §416.51(b) Standard: Infection control program.

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. [...] This Standard is NOT MET as evidenced by:

Observed in Infection Control System Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service. While the organization reports that no surgical site infections have surfaced there was no documentation to support the report.

Chapter:

Infection Prevention and Control

Program:

Ambulatory Health Care Accreditation

Standard:

IC.02.02.01

Standard Text:

The organization reduces the risk of infections associated with medical equipment,

devices, and supplies.

Element(s) of Performance:

2. The organization implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * (See also EC.02.04.03, EP 4) Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/ acknowledg.html (Sterilization and Disinfection in Healthcare Settings).



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

§416.51(a) - (Q-0241) - §416.51(a) Standard: Sanitary environment

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, WI) site for the Ambulatory Surgical Center deemed service. During review of the process of autoclave procedure it was noted that the organization did not document the time, pressure and temperature of the cycle used.

Chapter:

Leadership

Program:

Ambulatory Health Care Accreditation

Standard:

LD.01.03.01

Standard Text:

Governance is ultimately accountable for the safety and quality of care, treatment,

or services.

Element(s) of Performance:

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.99 Filed 07/13/17 Page 99 of 125

The Joint Commission

2. Governance provides for organization management and planning.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 2 §416.41 - (Q-0040) - §416.41 Condition for Coverage: Governing Body and Management This Condition is NOT MET as evidenced by:

Observed in Auto Score for CLD at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, Wi) site for the Ambulatory Surgical Center deemed service. The governing body/leadership did not ensure that the following Conditions of Participation were met as determined through observations, documentation, and staff interviews: §416.41 - (Q-0040), §416.44 - (Q-0100), §416.51 - (Q-0240)

Chapter:

Leadership

Program:

Ambulatory Health Care Accreditation

Standard:

LD.04.01.01

Standard Text:

The organization complies with law and regulation.

Element(s) of Performance:

15. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The organization complies with part 493 of the Code of Federal Regulations.

Note: Part 493 of the Code of Federal Regulations requires organizations who perform laboratory testing to maintain compliance with the Clinical Laboratory Improvement Amendments of 1988

(CLIA '88).

Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 15 §416.49(a) - (Q-0201) - §416.49(a) Standard: Laboratory Services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

The organization was not able to provide a valid CLIA certificate.

Chapter:

Life Safety

Program:

Ambulatory Health Care Accreditation

Standard:

LS.03.01.30

Standard Text:

The organization provides and maintains building features to protect individuals

from the hazards of fire and smoke.

Note 1: This standard applies to sites of care where four or more patients at the same time are provided either anesthesia or outpatient services that render patients incapable of saving themselves in an emergency in the organization. Note 2: This standard applies to all ambulatory surgical centers seeking accreditation for Medicare certification purposes, regardless of the number of

patients rendered incapable.

Note 3: In leased facilities, the elements of performance of this standard apply only to the space in which the accredited organization is located; all exits from the space to the outside at grade level; and any Life Safety Code building systems that support the space (for example, fire alarm system, automatic sprinkler system).

Element(s) of Performance:

5. All hazardous areas have sprinkler systems, resist the passage of smoke and have doors with self-closing or automatic-closing devices, or are enclosed with 1-hour fire-rated walls. (For full text and any exceptions, refer to NFPA 101-2000: 20/21.3.2 and 38/39.3.2.1)

Scoring Category: C

Score:

Partial Compliance

Observation(s):

§416.44(b)(1) - (Q-0104) - (1) Except as otherwise provided in this section, the ASC must meet the provision applicable to the ambulatory Healthcare Center of the 2000 edition of the Life Safety code of the National Fire protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the code is available for inspection at the CMS Information Recourse Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information o the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federalregister/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

The door located at the entrance to the soiled utility room was not equipped with a self closer.

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, WI) site for the Ambulatory Surgical Center deemed service.

The walls in the soiled utility room did not extend to the roof. The walls terminated a few inches above the drop ceiling. The facility was not equipped with an automatic sprinkler system.

Chapter:

Medication Management

Program:

Ambulatory Health Care Accreditation

Standard:

MM.01.01.03

Standard Text:

The organization safely manages high-alert and hazardous medications.

Element(s) of Performance:

1. The organization identifies, in writing, its highalert and hazardous medications. * (See also

EC.02.02.01, EP 8)

Note: This element of performance is also

applicable to sample medications.

Footnote *: For a list of high-alert medications, see

http://www.ismp.org. For a list of hazardous

medications, see

http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-

138 v3.pdf.

Scoring Category: A

Score:

Insufficient Compliance



2. The organization has a process for managing high-alert and hazardous medications. (See also EC.02.02.01, EP 8; MM.03.01.01, EP 9) Note: This element of performance is also applicable to sample medications.



Scoring Category:

Score:

Insufficient Compliance

Observation(s):

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, WI) site. The organization did not identify, in writing, its high-alert and hazardous medications.

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, IVII) site. Observed in maividual fraction at interventional Fam Center FLLO (21923 van Dyke, Suite B, Warren, MI) to the organization could not demonstrate a process for managing high-alert and hazardous medications.

Chapter:

Medication Management

Program:

Ambulatory Health Care Accreditation

Standard:

MM.01.02.01

Standard Text:

The organization addresses the safe use of look-alike/sound-alike medications.

Element(s) of Performance:

1. The organization develops a list of lookalike/sound-alike medications it stores, dispenses, or administers.

Note 1: One source of look-alike/sound-alike medications is The Institute for Safe Medication

(http://www.ismp.org/Tools/confuseddrugnames.pdf

Note 2: This element of performance is also applicable to sample medications.

Scoring Category:

Score:

Insufficient Compliance



Organization Identification Number: 596448

Page 26 of 44

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.103 Filed 07/13/17 Page 103 of 125

The Joint Commission

2. The organization takes action to prevent errors involving the interchange of the medications on its list of look-alike/sound-alike medications. Note: This element of performance is also applicable to sample medications.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 1

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, IIII) site. The organization could not produce a document of a list of look-alike/sound-alike medications it stores, dispenses, or administers.

EP2

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. The organization had no action plan in place to prevent errors involving the interchange of the medications on its look-alike/sound-alike medications.

Chapter:

National Patient Safety Goals

Program:

Ambulatory Health Care Accreditation

Standard:

NPSG.07.01.01

Standard Text:

Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand

hygiene guidelines.

Element(s) of Performance:

2. Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 2

Observed in Infection Control System Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B,

The infection control nurse could not show documentation of goals for improving compliance with hand hygiene guidelines.

Chapter:

National Patient Safety Goals

Program:

Ambulatory Health Care Accreditation

Standard:

UP.01.03.01

Standard Text:

A time-out is performed before the procedure.

Element(s) of Performance:

5. Document the completion of the time-out. Note: The organization determines the amount and type of documentation.

Scoring Category: C

Score:

Insufficient Compliance

Observation(s):

EP 5

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. In 24 of 24 During the individual tracers and chart review, it was noted that the time out documentation was not completed as the organization's time out policy stated.

Chapter:

Provision of Care, Treatment, and Services

Program:

Ambulatory Health Care Accreditation

Standard:

PC.03.01.03 -

Standard Text:

The organization provides the patient with care before initiating operative or other high-risk procedures, including those that require the administration of moderate or

deep sedation or anesthesia.

Element(s) of Performance:

14. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: A comprehensive medical history and physical assessment is completed for each patient by a physician (as defined in section 1861(r) of the Social Security Act) or other qualified practitioner, in accordance with applicable state health and safety laws, standards of practice, and organization policy.



Scoring Category: C

Score:

Insufficient Compliance

15. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: Each patient has a presurgical assessment completed upon admission by a physician or other qualified practitioner, in accordance with applicable state health and safety laws, standards of practice, and organization policy. This assessment includes any changes in the patient's condition since the patient's most recent medical examination, and documentation of any allergies to drugs and biologicals.



Scoring Category: C

Score:

Insufficient Compliance

Observation(s):

EP 14 §416.52(a)(1) - (Q-0261) - (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

In 26 of 26 patient records reviewed, it was noted that a comprehensive medical history and physical assessment is completed by the physician performing the procedure was not documented in the patient's chart.

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.107 Filed 07/13/17 Page 107 of 125

The Joint Commission

EP 15

§416.52(a)(2) - (Q-0262) - (2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals. This Standard is NOT MET as evidenced by:

Observed in Record Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

In 26 of 26 patient records reviewed, it was noted that the preanesthetic assessment was incomplete and missing information in several areas, such as vitals signs, height, weight, laboratory results review and review of systems.

Chapter:

Provision of Care, Treatment, and Services

Program:

Ambulatory Health Care Accreditation

Standard:

PC.03.01.05

Standard Text:

The organization monitors the patient during operative or other high-risk procedures and/or during the administration of moderate or deep sedation or anesthesia.

Element(s) of Performance:

1. During operative or other high risk procedures, including those that require the administration of moderate or deep sedation or anesthesia, the patient's oxygenation, ventilation, and circulation are monitored continuously. (See also RC.02.01.03, EP 8)



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP₁

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. In 26 of 26 during individual tracer and patient chart review, it was noted that EKG monitoring was not being performed and not noted as being performed whereas the policy entitled "Anesthesia - Use of anesthesia" stated "Patients are EKG monitored in the procedure room during the procedure."

Page 30 of 44

Chapter:

Provision of Care, Treatment, and Services

Program:

Ambulatory Health Care Accreditation

Standard:

PC.03.01.07

Standard Text:

The organization provides care to the patient after operative or other high-risk procedures and/or the administration of moderate or deep sedation or anesthesia.

Element(s) of Performance:

1. The organization assesses the patient's physiological status immediately after the operative or other high risk procedure and/or as the patient recovers from moderate or deep sedation or anesthesia. (See also RC.02.01.03, EP 8)



Scoring Category: A

Score:

Insufficient Compliance

5. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: Each patient is evaluated by a physician (as defined in section 1861(r) of the Social Security Act), or an anesthetist (as defined by law and regulation) for proper recovery before discharge from the ambulatory surgical center.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 1 §416.42(a)(2) - (Q-0062) - (2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery. This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

The medical assistant escorted the patient from the operating room to the post anesthesia care area where another medical assistant obtained a set of vital signs whereas the policy entitled "PACU - Patient Discharge" states "the PACU record must be completed and signed by the RN discharging the patient".

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.109 Filed 07/13/17 Page 109 of 125

The Joint Commission

EP 5

§416.42(a)(2) - (Q-0062) - (2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery. This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

After the procedural sedation was given by the Anesthesiologist, he did not document in the chart that the patient had adequately recovered from the sedation drugs administered.

Chapter:

Rights and Responsibilities of the Individual

Program:

Ambulatory Health Care Accreditation

Standard:

RI.01.01.01

Standard Text:

The organization respects patient rights.

Element(s) of Performance:

2. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The ambulatory surgical center informs the patient of his or her rights.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 2

§416.50 - (Q-0219) - §416.50 Condition for Coverage: Condition for coverage - Patient Rights This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service.

After observing care from front desk to discharge, no indication for this deemed facility that the patient had been informed of their rights and the discharge instructions state that the patient received a copy of said rights which was also not witnessed.

Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.110 Filed 07/13/17 Page 110 of 125

The Joint Commission

Chapter:

Rights and Responsibilities of the Individual

Program:

Ambulatory Health Care Accreditation

Standard:

RI.01.05.01

Standard Text:

The organization addresses patient decisions about care, treatment, or services

received at the end of life.

Element(s) of Performance:

1. The organization has written policies on advance directives.

Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP₁

§416.50(c)(1) - (Q-0224) - (1) Provide the patient or, as appropriate, the patient's representative prior to the start of the surgical procedure with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms. This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site for the Ambulatory Surgical Center deemed service. After document review and discussion with clinical leadership, it was determined there is no Advance Directive policy.

Chapter:

Waived Testing

Program:

Ambulatory Health Care Accreditation

Standard:

WT.01.01.01

Standard Text:

Policies and procedures for waived tests are established, current, approved, and

readily available.

Element(s) of Performance:

Page 33 of 44

2. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, establishes written policies and procedures for waived testing that address the followina:

 Clinical usage and limitations of the test methodology

- Need for confirmatory testing and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)

- Specimen type, collection, and identification, and required labeling

- Specimen preservation, if applicable

- Instrument maintenance and function checks, such as calibration

Storage conditions for test components

- Reagent use, including not using a reagent after its expiration date

- Quality control (including frequency and type) and remedial action

- Test performance

- Result reporting, including not reporting individual patient results unless quality control is acceptable

- Equipment performance evaluation Note: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.

Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 2

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. it was noted that the organization did not document a waived testing policy that addresses the following: clinical usage and limitations of the test methodology, need for confirmatory testing and result follow-up recommendations, specimen type, collection, and identification, and required labeling specimen preservation, instrument maintenance and function checks, storage conditions for test components, reagent use, quality control, test performance, result reporting, and equipment performance evaluation.

Chapter:

Waived Testing

Program:

Ambulatory Health Care Accreditation

Standard:

WT.03.01.01

Standard Text:

Staff and licensed independent practitioners performing waived tests are

competent.

Element(s) of Performance:

5. Competency for waived testing is assessed using at least two of the following methods per person per test:

- Performance of a test on a blind specimen

- Periodic observation of routine work by the

supervisor or qualified designee

Monitoring of each user's quality control performance

- Use of a written test specific to the test assessed

Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP 5

Observed in HR File Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. In 7 of 7 HR files reviewed, it was noted that competency for waived testing is assessed using at least two methods per person per test was not documented in the personnel file.

Chapter:

Waived Testing

Program:

Ambulatory Health Care Accreditation

Standard:

WT.05.01.01

Standard Text:

The organization maintains records for waived testing.

Element(s) of Performance:



Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.113 Filed 07/13/17 Page 113 of 125

The Joint Commission

3. Quantitative test result reports in the clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. Note 1: Semiquantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this element of performance. Note 2: If the reference intervals (normal values) are not documented on the same page as and adjacent to the waived test result, they must be located elsewhere within the permanent clinical record. The result must have a notation directing the reader to the location of the reference intervals (normal values) in the clinical record.



Scoring Category: A

Score:

Insufficient Compliance

Observation(s):

EP3

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, I/II) site. It was noted that the reference intervals for the glucose and PT/INR results are not documented in the patient's chart.

Opportunities for Improvement - Summary

Observations noted within the Opportunities for Improvement (OFI) section of the report represent single instances of non-compliance noted under a C category Element of Performance. Although these observations do not require official follow up through the Evidence of Standards Compliance (ESC) process, they are included to provide your organization with a robust analysis of all instances of non-compliance noted during survey.

Program:	Ambulatory Health Care Accreditation Program	
Standards:	IC.02.02.01.	EP1
-	LD.04.02.01	EP6
	LS.03.01.10	EP9
4-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	LS.03.01.34	EP6
	MM.03.01.01	EP2
	PC.03.01.03	EP16
	PC.03.01.07	EP9
•	RC.02.01.01	EP2

Opportunities for Improvement - Detail

Chapter:

Infection Prevention and Control

Program:

Ambulatory Health Care Accreditation

Standard:

IC.02.02.01

Standard Text:

The organization reduces the risk of infections associated with medical equipment,

devices, and supplies.

Element(s) of Performance:

1. The organization implements infection prevention and control activities when doing the following: Cleaning and performing low-level disinfection of medical equipment, devices, and supplies. * Note: Low-level disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions. Footnote *: For further information regarding cleaning and performing low-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/ acknowledg.html.

Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. It was noted that the medical assistant used a blood pressure cuff on a patient and replaced the cuff into the monitor basket without performing low-level disinfection.

Chapter:

Leadership

Program:

Ambulatory Health Care Accreditation

Standard:

LD.04.02.01

Standard Text:

The leaders address any conflict of interest involving licensed independent practitioners and/or staff that affects or has the potential to affect the safety or quality

of care, treatment, or services.

Element(s) of Performance:

6. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The ambulatory surgical center discloses, where applicable, physician financial interests or ownership in the facility in accordance with 42 CFR Part 420. This disclosure information is in writing.



Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. It was noted that the organization did not document disclosure of physician financial interest or ownership in the facility.

Chapter:

Life Safety

Program:

Ambulatory Health Care Accreditation

Standard:

LS.03.01.10

Standard Text:

Building and fire protection features are designed and maintained to minimize the

effects of fire, smoke, and heat.

Note 1: This standard applies to sites of care where four or more patients at the same time are provided either anesthesia or outpatient services that render patients

incapable of saving themselves in an emergency in the organization. Note 2: This standard applies to all ambulatory surgical centers seeking accreditation for Medicare certification purposes, regardless of the number of

patients rendered incapable.

Note 3: In leased facilities, the elements of performance of this standard apply only to the space in which the accredited organization is located; all exits from the space to the outside at grade level; and any Life Safety Code building systems that support

the space (for example, fire alarm system, automatic sprinkler system).

Element(s) of Performance:

9. The space around pipes, conduits, bus ducts, cables/wires, air ducts, or pneumatic tubes that penetrate fire-rated walls and floors are filled with an approved fire-rated material.

Note: Polyurethane expanding foam is not an accepted fire-rated material for this purpose. (For full text and any exceptions, refer to NFPA 101-

2000: 8.2.3.2.4.2)

Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):



EP9

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. There was a duct penetration located above the door at the entrance to procedure room 2.

Chapter:

Life Safety

Program:

Ambulatory Health Care Accreditation

Standard:

LS.03.01.34

Standard Text:

The organization provides and maintains fire alarm systems.

Note 1: This standard applies to sites of care where four or more patients at the same time are provided either anesthesia or outpatient services that render patients

incapable of saving themselves in an emergency in the organization. Note 2: This standard applies to all ambulatory surgical centers seeking accreditation for Medicare certification purposes, regardless of the number of

patients rendered incapable.

Note 3: In leased facilities, the elements of performance of this standard apply only to the space in which the accredited organization is located; all exits from the space to the outside at grade level; and any Life Safety Code building systems that support

the space (for example, fire alarm system, automatic sprinkler system).

Element(s) of Performance:

6. The organization meets all other Life Safety Code fire alarm requirements related to NFPA 101-2000: 20,3,4/21.3.4.

Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):

Observed in Building Tour at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. The main fire alarm control panel cabinet was not labeled with the circuit breaker that controlled power to the panel.

Chapter:

Medication Management

Program:

Ambulatory Health Care Accreditation

Standard:

MM.03.01.01

Standard Text:

The organization safely stores medications.

Page 40 of 44

Element(s) of Performance:

2. The organization stores medications according to the manufacturers' recommendations. Note: This element of performance is also applicable to sample medications.



Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. It was noted that the refrigerator temperature monitoring was not documented when the organization was open and closed.

Chapter:

Provision of Care, Treatment, and Services

Program:

Ambulatory Health Care Accreditation

Standard:

PC.03.01.03

Standard Text:

The organization provides the patient with care before initiating operative or other high-risk procedures, including those that require the administration of moderate or

deep sedation or anesthesia.

Element(s) of Performance:

16. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: A physician or other qualified practitioner, in accordance with applicable state health and safety laws, standards of practice, and organization policy, examines the patient immediately before surgery to evaluate patient risk for the procedure to be performed.



Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, III) site. It was noted that the physician performing the procedure did not examine the patient before the procedure.

Chapter:

Provision of Care, Treatment, and Services

Program:

Ambulatory Health Care Accreditation

Standard:

PC.03.01.07

Page 41 of 44

Standard Text:

The organization provides care to the patient after operative or other high-risk procedures and/or the administration of moderate or deep sedation or anesthesia.

Element(s) of Performance:

9. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The ambulatory surgical center completes the appropriate postsurgical assessments for each patient, including all elements required for discharge.



Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):

EP9

Observed in Individual Tracer at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. The physician who performed the procedure did not write a discharge order and the nurse did not complete the discharge process including the medication reconciliation process.

Chapter:

Record of Care, Treatment, and Services

Program:

Ambulatory Health Care Accreditation

Standard:

RC.02.01.01

Standard Text:

The clinical record contains information that reflects the patient's care, treatment, or

services.

Element(s) of Performance:

- 2. The clinical record contains the following clinical information:
- The patient's initial diagnosis, diagnostic impression(s), or condition(s)
- Any findings of assessments and reassessments (See also PC.01.02.01, EPs 1 and 4; PC.03.01.03, EPs 1 and 8)
- Any allergies to food
- Any allergies to medications
- Any conclusions or impressions drawn from the patient's medical history and physical examination - Any diagnoses or conditions established during the patient's course of care, treatment, or services
- Any consultation reports
- Any progress notes
- Any medications ordered or prescribed
- Any medications administered, including the strength, dose, and route
- Any access site for medication, administration devices used, and rate of administration
- The patient's response to any medication administered
- Any adverse drug reactions
- Plans for care and any revisions to the plan for care (See also PC.01.03.01, EP 1)
- Orders for diagnostic and therapeutic tests and procedures and their results

Scoring Category: C

Score:

Satisfactory Compliance

Observation(s):

Observed in Document Review at Interventional Pain Center PLLC (27423 Van Dyke, Suite B, Warren, MI) site. It was noted that the patient chart has no mechanism for the physician to order the waived testing.



Case 2:17-cv-11644-LJM-SDD ECF No. 1, PageID.121 Filed 07/13/17 Page 121 of 125

The Joint Commission

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EXHIBIT E

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30

Monthly Patient Monitoring Equipment Procedure Room Monitor

Refrigerator Temperature Log

Date	Time	Recorded By	Internal Temp	Range	Clear Memory	Corrective Actions
5-17	11'.00	Deni	40°F	37-44	A	
248	1(3,70		40°F	38-44		
5-19	11:30		40°F	4044	À	
5 - 20	11:30	·	hor	40-44		
5-2	210,0		40°F	40-44	Æ.	
5-23	८०,∞		40F	40-44	JZ/	
5-24	10.00		40°F	40-44	AL .	
5-25	11.00		400F	39-44	<i>A</i>	
5-26	11:30		40°F	39-44		
S-Z7	11:30		40°F	39-44		<u> </u>
2-29	11:30		4000	39-44	ك_	
5-30	11:30	-	HO°F	39-44		
5-31	11:30		40°F	39-44		
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Refrigerator Temperature Log

Date	Time	Recorded By	Internal Temp	Range	Clear Memory	Corrective Actions
4-22	11:00	, Deni	40F	37-44	A	
4-24	10,00	1	409	37-44		
4-25	10,00		402	37-44	R	
4-26	(0,0)		40F	37-44	A	1444
4-27	(0'.30		40°F	37-44	R	
4-28	10.30		40%	37-44	A	
4-29	10:30		40°F	37-44	R	
5-1	10:00		404	37-44	9	
5-2	(0'.00)		40°F	37-44	A	
5-3	(0,00		40°F	37-44	4	
5-4	(0:00		_	37-44	A	
5-5	10,20			37-44	R	
5-6	1:00			37-44	A.	
5-8	1(30			37-44	Q.	
5-9	0,20			37-44	9	
570	10.00			37-44	9	
5-11				37-44	9	
572	10:00			37-44	凤	
5-13/	1:00			37-44	8	
5-15	11:00		\	37-44	a	
5-161	1:00	V	V	37-44	AX.	